IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

IN RE: C. R. BARD, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**MDL NO. 2187**
THIS DOCUMENT RELATES TO:	
CAROLYN JONES,	**2:11-cv-00114**
v.	
C. R. BARD, INC.	

DEFENDANT C. R. BARD, INC.'S MEMORANDUM OF LAW IN OPPOSITION TO PLAINTIFF'S MOTION FOR PARTIAL SUMMARY JUDGMENT ON DEFENDANT'S AFFIRMATIVE DEFENSES

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INTRODUCTION

Defendant C. R. Bard, Inc. ("Bard") respectfully requests this Court deny Plaintiff's Motion for Partial Summary Judgment on Bard's Affirmative Defenses (the "Motion"). Plaintiff's Motion challenges eight of Bard's affirmative defenses concerning contributory negligence, comparative fault, assumption of risk, mitigation of damages, and federal preemption. The Court should deny Plaintiff's Motion for two primary reasons.

First, the Motion is premature. Discovery is continuing and ongoing. In accordance with the parties' agreement prior to the close of discovery, the depositions of five fact witnesses still need to be taken.[1] Of the 13 expert witnesses identified by Bard, only three (3) have been fully deposed to date. Additionally, Plaintiff recently served a "supplemental/rebuttal" report for two of her expert witnesses (Dr. Hoyte and Dr. El-Ghannam) and also identified two "rebuttal" expert witnesses (Dr. King and Dr. Ostergard). Until discovery is completed, it is premature for Plaintiff to challenge Bard's ability to support its affirmative defenses.[2]

Second, Plaintiff fails to sustain her burden of proof. As to many of the defenses that are the subject of Plaintiff's Motion, an issue of fact precludes the granting of summary judgment. Additionally, Plaintiff's Motion lacks evidentiary support. Plaintiff relies exclusively on Ms. Jones' deposition and a section titled "General Case Background." This section is nothing more than unsubstantiated argument; none of the assertions in this section are supported by a

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[1] In a letter dated April 5, 2013 ("April Letter"), Bard requested dates for the depositions of Dr. Michael Fox, Dr. Nannette Pinkard, Linda Moffit (Ms. Jones' sister), Candy Pannell (Ms. Jones' sister), and Christopher Jones (Ms. Jones' son). A true and correct copy of the April Letter is annexed hereto as Exhibit A.

[2] Bard recognizes the importance of streamlining the trial of this case to the extent possible, and Bard has no intention of complicating the trial with unnecessary and inapplicable affirmative defenses. Once discovery is complete, Bard is willing to confer with Plaintiff to winnow its affirmative defenses. As a starting point, Bard voluntarily withdraws Affirmative Defense No. 6 and Affirmative Defense No. 12, both of which relate to contributory negligence. Bard does not withdraw Affirmative Defense No. 14 to the extent it relates to comparative negligence/fault, which is addressed in Section II(A), *infra*.

single shred of evidence. Accordingly, the Court should not consider this section because it lacks the evidentiary basis required for a motion for summary judgment.

STATEMENT OF FACTS

The background and historical facts that give rise to this dispute are set forth in Bard's Memorandum of Law in Support of Motion for Partial Summary Judgment against Plaintiff Carolyn Jones. In the interest of brevity, Bard respectfully refers the Court to those facts, which it incorporates by reference as if fully set forth herein. To the extent Bard's opposition to Plaintiff's Motion requires additional facts, only those facts are set forth below.[3]

A. Ms. Jones Consented to the Risks of the Avaulta™ System and the Align® Urethral Sling.

Ms. Jones signed two consent forms prior to the surgery to implant her Avaulta™ System (the "Avaulta Consent") and her Align® urethral sling (the "Align Consent").[4] (Deposition of Carolyn Jones ("Jones Dep.") at174:6-12; 169:18-25; Deposition of David Williams, M.D. ("Williams Dep.") at 59:6-8.)[5] The Avaulta Consent, in addition to the general risks associated with all surgeries, specifically identified the following risks for her anterior and posterior repair: damage to the bladder or bowel which would require further surgery, difficulty in emptying the bladder, painful intercourse, damage to the ureter, a hole may form between the bladder and the vagina which could require further surgery, the procedure may make urinary leakage with coughing or sneezing worse, the cytokine may reoccur at some later date, perforation of the

[3] For the avoidance of any doubt, this section is not intended to provide an exhaustive list of every factual dispute. Rather, the facts set forth herein are intended to provide *examples* of the genuine issues of fact the existence of which requires the denial of Plaintiff's Motion.

[4] A true and correct copy of Ms. Jones' Avaulta Consent is annexed hereto as Exhibit B (JONESC_WCNAL_MDR00026-27). A true and correct copy of Ms. Jones' Align Consent is annexed hereto as Exhibit C (JONESC_WCNAL_MDR00023-25).

[5] A true and correct copy of Ms. Jones' deposition transcript was previously filed with the Court as an Exhibit to Bard's Motion for Partial Summary Judgment against Jones on April 1, 2013 (ECF 148-1 and 148-4). A true and correct copy of Dr. Williams' deposition transcript was previously filed with the Court as an Exhibit to Bard's Motion for Partial Summary Judgment against Jones on April 1, 2013 (ECF 148-2).

rectum requiring further surgery, a hole between the rectum and the vagina may form requiring further surgery, loss of ability to control stool, and complete relief is not obtained in all cases and in some cases the rectocele may reoccur and it may be accompanied by additional presence of enterocele (hernia). Similarly, the Align Consent specifically warns of the following risks associated with the suburethral sling procedure: damage to the bladder or bowel could result in more extensive surgery than anticipated or return to the operating room for additional surgery, difficulty emptying your bladder, pain with intercourse, damage to the ureter or urethra, fistula formation that could require further surgery, failure of the surgery to completely stop the leakage or even make the leakage worse, and the stress urinary incontinence could recur later in life.

B. Ms. Jones failed to take steps to improve her health.

Ms. Jones had numerous medical conditions prior to her pelvic mesh surgery. Ms. Jones testified she was being treated for diabetes for about 12 or 14 years prior to her surgery. (Jones Dep. 219:3-5.) Ms. Jones is also obese and testified that she knew she needed to lose weight, but she "wasn't trying to." (Jones Dep. 83:1-8). Ms. Jones also suffered from chronic obstructive pulmonary disease (COPD) and received Social Security Disability payments due to her COPD and uncontrolled diabetes. (Jones Dep. 63:5-9.) Hilary Cholhan, M.D., one of Bard's experts, provided in his Rule 26 Expert Report (the "Cholhan Report")[6] that as of 2008, pre-implant, Ms. Jones suffered from numerous medical conditions, including uncontrolled insulin-dependent Type II diabetes with retinopathy, obesity, restrictive pulmonary disease, hypertension, hyperlipidemia, gastro-esophageal reflux disease with hiatal hernia, restless leg syndrome, anxiety/depressive disorder, osteoarthritis, venous insufficiency, coronary arterial disease, chronic lower back pain, history of smoking, and vulvovaginal candidiasis. (*See* Cholhan

[6] A true and correct copy of Dr. Cholhan's Rule 26 Expert Report is annexed hereto as Exhibit D.

Report, p. 18-19). Some of these conditions can be risk factors for recurring pelvic organ prolapse, poor candidacy for pelvic mesh surgery, and/or poor surgical outcome.

C. Ms. Jones failed to follow her physician's recommendations.

There is no evidence that Ms. Jones took any steps to determine if it was possible to avoid additional surgery or first try less non-invasive options following her mesh implant. Dr. Stephen Farmer referred Ms. Jones for a second opinion from a reconstructive urology specialist. (*See* September 9, 2009 Office Note of C. Stephen Farmer, MD, JONESC_UPA_MDR00037.)[7] Ms. Jones declined to go out of town to be evaluated by this specialist. (*See id.*; *see also* Cholhan Rep. at p. 21.)

Ms. Jones was also told by a pain management physician that she should get shots in her back to treat her complaints of pain. (*See* Jones Dep. at 222:13-18.) She refused to get the shots to treat her pain and never went back to the pain management specialist. (*See id.*) Similarly, Ms. Jones was referred to a women's health urogynecologist specialist, Dr. Valerie Vogt. (*See* July 15, 2011 Patient Summary Note of Valerie Vogt, M.D., JONESC_WHS_MDR00004.)[8] Dr. Vogt told Ms. Jones that surgery would not help her back pain. (*See id.*) Following this visit with Dr. Vogt, Ms. Jones decided to stop seeing Dr. Vogt because she felt Dr. Vogt was dismissive. **(**Jones Dep. at 210:1-2.)

D. Ms. Jones' implanting physician, Dr. Williams, failed to properly evaluate Ms. Jones as a transvaginal mesh surgical candidate and did not provide a detailed report of her surgery.

According to Dr. Cholhan, Ms. Jones was not an appropriate candidate for pelvic mesh surgery due to her numerous medical conditions. (Cholhan Rep. at p. 23). David Williams,

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[7] A true and correct copy of the September 9, 2009 Office Note of C. Stephen Farmer, M.D., JONESC_UPA_MDR00037 ("Farmer Note") is annexed hereto as Exhibit E.

[8] A true and correct copy of the July 15, 2011 Patient Summary Note of Valerie Vogt, M.D., JONESC_WHS_MDR00004 ("Vogt Note") is annexed hereto as Exhibit F.

M.D., the physician who performed her mesh surgery, failed to accurately evaluate Ms. Jones as a surgical mesh candidate. (*See id.*) Further, neither Ms. Jones' medical records nor Dr. Williams' deposition testimony provide any evidence that Ms. Jones was appropriately counseled regarding alternative treatment options prior to her transvaginal surgery. (*See id.* at 22.)

Dr. Williams operative note lacks important details that would explain whether or not the surgery was performed in an appropriate manner. For instance, his operative note does not contain information regarding:

- the instruments used for the placement of the mesh products in Ms. Jones;
- the degree of upward traction or tension placed on the sling;
- how the degree of upward traction or tension may have been achieved by Dr. Williams;
- how the degree of upward traction or tension may have been proofed by Dr. Williams;
- whether Dr. Williams irrigated the surgical site; or
- the degree of hemostasis.

(Cholhan Rep. at p. 20.) Dr. Williams was unable to provide any clarity on these issues in his deposition. (*See* Williams Dep. at 59:17-67:19.)

LEGAL STANDARD

Summary judgment is appropriate after "adequate time for discovery" and only when the pleadings, depositions, and affidavits submitted by the parties show that no genuine issue of material fact exists and that the movant is entitled to judgment as a matter of law. *See Celotex Corp. v. Catrett*, 477 U.S. 317, 322, 106 S. Ct. 2548, 2552, 91 L. Ed. 2d 265 (1986); Fed. R. Civ. P. 56(c). In determining whether a genuine dispute of material fact exists to defeat a motion for summary judgment, the evidence is viewed in the light most favorable to the party opposing

summary judgment, drawing all justifiable inferences in the opposing party's favor. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255, 106 S. Ct. 2505, 91 L.Ed.2d 202 (1986). A fact is material if it is relevant or necessary to the outcome of the suit. *Id*. at 248. A factual dispute is genuine if the evidence would allow a reasonable jury to return a verdict for the nonmoving party. *Id*.

ARGUMENT

I. PLAINTIFF'S MOTION IS PREMATURE BECAUSE CONSIDERABLE DISCOVERY REMAINS.

Plaintiff's Motion is premature because considerable discovery—both fact and expert—remains pending. At least five additional fact witnesses, including two physicians, must be deposed. Bard has requested dates for these depositions, and is presently awaiting a response from counsel for Plaintiff. (*See* April Letter.) Additionally, expert discovery is not yet complete. Of the 13 expert witnesses identified by Bard, only three (3) have been fully deposed to date.[9]

Here, of the many expert depositions still to be taken, perhaps none are more important to this motion than that of Vincent Lucente, M.D. and Hilary Cholhan, M.D., Bard's urogynecology expert witnesses. Although Dr. Lucente's deposition began on March 15, 2013, it could not be concluded on that day.[10] As a result, Dr. Lucente has not yet completed his testimony. Plaintiff has yet to complete even the *first* day of Dr. Cholhan's deposition. Dr. Cholhan's deposition was adjourned upon Plaintiff's request, and it is now scheduled for May 13, 2013.

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[9] In accordance with PTO #59 and #72, Bard provided deposition dates in March and April for all its expert witnesses. Although Plaintiff initially accepted dates during this period, most of those dates have since been pushed back at Plaintiff's request.

[10] The parties are in the process of scheduling the second day of his deposition. Bard has proposed May 10, 2013; Plaintiff's attorneys have not yet confirmed whether they intend to proceed on this date.

The facts and opinions that may be developed during the remainder of Dr. Lucente's deposition (and the entirety of Dr. Cholhan's deposition) bear directly on the issues raised in Plaintiff's Motion. For example, Dr. Cholhan will likely testify about Ms. Jones' conduct and course of treatment post-implant, her decision to have the mesh removed, her compliance with her doctor's instructions, and the effect of that compliance on her health. Such testimony may therefore implicate Ms. Jones' comparative fault, the possible fault of others, and Ms. Jones' efforts to mitigate her damages. Plaintiff's Motion operates to force Bard to disclose the specific opinions of its expert witnesses before those witnesses have been deposed. Plaintiff is not entitled to such a pre-deposition preview, and Plaintiff's Motion is premature for this reason alone.

Additionally, Plaintiff continues to inject new issues into the case. On April 1, 2013, Plaintiff served alleged "supplemental" reports for Dr. Hoyte[11] and Dr. El-Ghannam. Plaintiff also served alleged "rebuttal" reports by two new expert witnesses, Dr. King and Dr. Ostergard.[12] If Plaintiff's supplemental and rebuttal reports are permitted over Bard's objections, Bard may need to further supplement the reports of its own expert witnesses. In that event, new facts and opinions pertinent to this case may be discovered and developed.

In sum, continuing discovery is likely to reveal additional facts and opinions that preclude granting summary judgment against Bard's affirmative defenses. Bard is entitled to rely upon a complete record to respond to Plaintiff's Motion. Plaintiff cannot deprive Bard of that

[11] As noted in Bard Reply Memorandum of Law in Support of its Motion to Limit the Opinions and Testimony of Lennox Hoyte, M.D., Dr. Hoyte's alleged "supplemental" does not actually supplement Bard's opinions. To the contrary, it provides entirely new opinions—based on newly reviewed materials—that Plaintiff was required to disclose by October 15, 2012. Bard therefore reserved the right to object to or otherwise move to strike Dr. Hoyte's "supplemental report." Untimeliness aside, Dr. Hoyte's new opinions are inadmissible under *Daubert* and should be excluded for the reasons discussed in Bard's Motion to Exclude.

[12] Bard is moving to strike the alleged "rebuttal" reports of Dr. King and Dr. Ostergard in papers filed contemporaneously herewith.

opportunity by moving for summary judgment prior to the close of discovery; the completion of which has been delayed at Plaintiff's own request. Therefore, Plaintiff's Motion is premature and Bard requests the Court deny Plaintiff's Motion in its entirety.

II. EVEN IF PLAINTIFF'S MOTION WERE TIMELY, THE COURT SHOULD DENY THE MOTION BECAUSE GENUINE ISSUES OF FACT EXIST AS TO EACH OF BARD'S AFFIRMATIVE DEFENSES.

A. Bard is entitled to present evidence of the comparative negligence of Plaintiff or third persons.

By statute, Mississippi is a pure comparative negligence state:

> In all actions hereafter brought for personal injuries, or where such injuries have resulted in death, or for injury to property, the fact that the person injured, or the owner of the property, or person having control over the property may have been guilty of contributory negligence shall not bar a recovery, but damages shall be diminished by the jury in proportion to the amount of negligence attributable to the person injured, or the owner of the property, or the person having control over the property.

Miss. Code Ann. § 11-7-15. Under Mississippi's formulation of comparative negligence, a plaintiff's recovery will be reduced by the percent of the plaintiff's own negligence as determined by the jury. *Burton by Bradford v. Barnett*, 615 So.2d 580, 582 (Miss. 1993).

Here, the facts demonstrate that Ms. Jones and unrelated non-parties may have contributed to Ms. Jones' alleged outcome.[13] Consequently, Bard should be entitled to develop these facts and to present them and the relevant affirmative defenses to a jury at trial.

1. Comparative fault of Ms. Jones.

Ms. Jones failed to take efforts to adequately address the pre-existing medical conditions she had both before and after her pelvic mesh surgery. The record demonstrates that this failure may have contributed to her alleged injuries and conditions in this case. Dr. Cholhan notes Ms.

[13] As noted above (*see* fn. 3, *supra*), this Memorandum of Law is not intended to provide an exhaustive list of the issues of fact that preclude summary judgment on Bard's affirmative defenses. Rather, the facts described herein are intended to be *exemplary* of the justification for denying Plaintiff's Motion.

Jones had multiple medical conditions prior to her surgery, including: uncontrolled insulin-dependent Type II diabetes with retinopathy, obesity, restrictive pulmonary disease, hypertension, hyperlipidemia, gastro-esophageal reflux disease with hiatal hernia, restless leg syndrome, anxiety/depressive disorder, osteoarthritis, venous insufficiency, coronary arterial disease, chronic lower back pain, history of smoking, and vulvovaginal candidiasis. (*See* Cholhan Report, at p. 18-19.) Some of these conditions can be risk factors for recurring pelvic organ prolapse, *e.g.*, obesity. Discovery in this case has not been completed and it is anticipated that some of the outstanding witness depositions, including the testimony of defense expert Dr. Cholhan, may identify these conditions and Ms. Jones' actions or inactions as factors contributing to the cause of her alleged injuries. As such, there is an issue of fact about whether Ms. Jones bears at least some responsibility for any worsening of her health in that she failed to adequately address or treat these conditions and/or heed the instructions of her physicians.

2. Comparative fault of third persons.

Plaintiff's Motion concedes that Mississippi law allows the apportionment of damages amongst joint tortfeasors. (*See* Plaintiff's Motion, at p. 6 (citing Miss. Code. Ann. § 85-5-7).) Plaintiff merely argues that "Bard has pointed to no evidence of conduct, which if believed by the jury, would constitute negligence on the part of any non-party." (Plaintiff's Motion, at p. 6.) This argument fails because, although discovery in this case is still ongoing, there is already sufficient evidence in the record before this Court that third parties may be at fault.

David Williams, M.D. may bear some responsibility for Ms. Jones' damages. As an initial matter, because of Ms. Jones' multiple medical conditions, especially her advanced uncontrolled insulin-dependent diabetes with retinopathy, she was not an appropriate candidate for transvaginal surgery with mesh. (Cholhan Report at p. 23.) In addition, Dr. Williams' operative note is missing important details, which may signify that the pelvic mesh surgery was

not performed in a manner that was appropriate and acceptable. (Cholhan Report at p. 23.) The fact that Dr. Williams recommended transvaginal surgery for Ms. Jones and may not have appropriately performed the surgery may mean that he may well bear some responsibility for Ms. Jones' present claims.

B. Bard is entitled to present evidence that Plaintiff assumed the risk.

It is undisputed that Ms. Jones signed two consent forms prior to the surgery to implant Bard's products. (*See* the Avaulta Consent and the Align Consent.) Those consent forms specifically identify the possible risks associated with Bard's mesh products, including the very same risks about which Plaintiff now complains. Plaintiff's Motion does not acknowledge that Ms. Jones did in fact consent to the transvaginal mesh procedure and that she was advised of the risks disclosed in the consent forms. Despite this evidence in the record before the Court, Plaintiff claims the assumption of risk defense must be dismissed because there is *no* evidence:

- "Ms. Jones had knowledge that the Avaulta Plus product was *defective and inconsistent with its safety*";
- Ms. Jones "appreciated the *dangerous condition* of the product";
- "she deliberately and voluntarily 'exposed herself to the *dangerous condition*' in such a manner to register assent on the continuance of the *dangerous condition*;" and
- "Ms. Jones freely and voluntary [sic] chose to encounter a *dangerous condition* from a willing mental state.

(Motion at p. 7, emphasis added.) In other words, Plaintiff's argument for dismissing this defense presupposes the finding that Bard's products were defective and/or dangerous.

Plaintiff is putting the cart before the horse. As Plaintiff well knows, there has been *no determination* that the Avaulta Plus product implanted in Ms. Jones was in fact defective.

Indeed, Plaintiff has not moved for summary judgment on this point.[14] Here, Plaintiff is asking this Court to assume, absent any evidence, that the Avaulta Plus was defective and based on that assumption to foreclose Bard's ability to present evidence that Ms. Jones assumed the risks. This is contrary to the evidence, and Plaintiff's Motion should therefore be denied as to this point.

C. Bard is entitled to present evidence that Plaintiff failed to mitigate her alleged damages.

It is well established under Mississippi law that "a party has a duty to mitigate its damages." *Illinois Central Railroad v. Winters*, 863 So. 2d 955, 959 (Miss. 2004); *see also Flight Line, Inc. v. Tanksley*, 608 So. 2d 1149, 1162 (Miss. 1992); *Pelican Trucking Co. v. Rossetti*, 167 So. 2d 924, 927 (1964) ("One suing for damages is required to minimize his loss."); *Yazoo & M.V.R. Co. v. Fields*, 195 So. 489, 490 (Miss. 1940). "Without question, a person injured in tort is required to take reasonable steps to mitigate his damages, and this, at the very least, includes giving attention to doctor's orders regarding his course of recovery." *Tanksley*, 608 So.2d at 1162-1163 (citing *Reikes v. Martin*, 471 So.2d 385, 389 (Miss. 1985)).

Here, there is evidence to support a finding that Ms. Jones failed to take reasonable efforts to avoid the damages she allegedly sustained and allegedly continues to sustain. Further, it is anticipated that additional evidence may be discovered during the upcoming depositions of Dr. Lucente, Dr. Cholhan, Dr. Michael Fox, Dr. Nannette Pinkard, Linda Moffit, Candy Pannell, and Christopher Jones, in addition to other witnesses.

Although Plaintiff asserts that there is no evidence that Ms. Jones failed to take reasonably diligent steps to mitigate her damages, there is sufficient evidence in the record to

[14] Plaintiff's reliance on *Green v. Allendale Planting Co.*, 954 So.2d 1032, 1041 (Miss. 2007) is entirely misplaced. In *Green*, the defendant had moved for summary judgment on the grounds that the plaintiff had assumed the risk *as a matter of law*.

support a finding that she failed to mitigate her damages. (Plaintiff's Motion, p. 8.) For example:

- Ms. Jones refused to get a second opinion from a reconstruction urologist despite a referral from her treating physician,
- refused to get shots in her back to treat her pain as recommended by her pain management physician, and
- stopped going to one of her specialists because she found her to be dismissive.

First, Dr. Stephen Farmer, Ms. Jones' treating physician in the years following her implant surgery, referred Ms. Jones for a second opinion with a reconstruction urologist specialist. (*See* Farmer Note.) However, Ms. Jones declined to go out of town to be evaluated by this specialist. (*See id.*; *see also* Cholhan Rep. at p. 21.) Ms. Jones' failure to get a second opinion regarding her alleged problems with her sling, resulted in another surgery that may not have been the best course of treatment for her. Ms. Jones could have mitigated her damages by seeking a second opinion prior to proceeding with additional surgery. There is no evidence that Ms. Jones took any steps to even see if it was possible to avoid additional surgery or first try less non-invasive options.

Second, Ms. Jones claims that she had severe back pain following her implant surgery. (*See* Jones Dep. at 225:13-15 (". . . it's not a day that goes by that I'm not in pain.").) She testified at her deposition that she went to see a pain management physician and he recommended that she get shots in her back to help with her pain. (*See* Jones Dep. at 222:13-18.) Despite this recommendation, Ms. Jones refused to get the shots to treat her pain and never went back to that physician. (*See id.*) If Ms. Jones followed her physician's advice, she may have relieved her pain. Similarly, if Ms. Jones had continued seeing a pain management

physician, she may have had more success managing her pain. Her failure to take steps to alleviate her pain may be evidence of a failure to mitigate her alleged damages in this case.

Finally, Ms. Jones was referred to Valerie Vogt, M.D., a women's health urogynecologist specialist, for evaluation of her recurrent urinary tract infections including her main complaint of back pain. (*See* Vogt Note.) Dr. Vogt explained to Ms. Jones that surgery to remove the mesh would not help her back pain. *See id.* Ms. Jones testified that following this visit, she decided to stop seeing Dr. Vogt because she felt Dr. Vogt "acted like wasn't nothing [sic] wrong with me." (Jones Dep. at 210:1-2.) Ms. Jones' failure to follow-up with Dr. Vogt may also be a failure to mitigate her alleged damages.

D. Bard is entitled to assert its affirmative defense based on federal preemption to prophylactically guard against any latent "fraud on the FDA" claims.

Bard raised an affirmative defense that Plaintiff's claims are barred in part by federal preemption and that granting relief would impermissibly infringe upon and conflict with federal law, regulations, and policies in violation of the Supremacy Clause of the United States Constitution. (Bard's Aff. Def. No. 26.) Plaintiff argues that the holding of *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996) undercuts any argument that their state tort claims are preempted by federal law. (Motion at 8.) But *Lohr* is an *express* preemption case.

There is substantial case law holding that Plaintiff's claims are barred in part under *implied* preemption principles. For example, in *Buckman v. Plaintiffs' Legal Committee*, the Supreme Court held that the Federal Food, Drug and Cosmetic Act (the "FDCA") and the Medical Device Amendments ("MDA") to the FDCA preempt any state tort law claims of fraud on the FDA or any right of action of a private plaintiff based on regulatory violations against manufacturers, because enforcement of FDA regulations is exclusively within the province of the FDA. 531 U.S. 341, 348-53 (2001). As codified at 21 U.S.C. § 337(a), the MDA expressly assert

that all actions to enforce FDA requirements "shall be by and in the name United States." *See also Bailey v. Johnson,* 48 F.3d 965, 968 (6th Cir. 1995) ("Congress did not intend, either expressly or by implication, to create a private cause of action under the FDCA.").

The Court held in *Buckman* that "state-law fraud-on-the-FDA claims conflict with, and are therefore impliedly pre-empted by, federal law." 531 U.S. at 348. "[T]he §510(k) process sets forth a comprehensive scheme for determining whether an applicant has demonstrated that a product is substantially equivalent to a predicate device." *Id.* In *Medtronic,* plaintiffs alleged that a manufacturer had deceived the FDA by breaking a device down into its component parts and submitting the components for clearance, even after the FDA had refused clearance for the assembled device. *Id.* at 345-46. But the Court noted that "the §510(k) process imposes upon applicants a variety of requirements that are designed to enable the FDA to make its statutorily required judgment as to whether the device qualifies under this exception." *Id.* at 348-49.

Moreover, the FDCA contains "provisions aimed at detecting, deterring, and punishing false statements made during this and related approval processes." *Id.* at 349. The FDA is empowered to punish any violations of its regulations; to allow state law tort claims would interfere with this enforcement regiment. As the Supreme Court put it, "the federal statutory scheme amply empowers the FDA to punish and deter fraud against the Administration, and that this authority is used by the Administration to achieve a somewhat delicate balance of statutory objectives. The balance sought by the Administration can be skewed by allowing fraud-on-the-FDA claims under state tort law." *Id.* at 348.

The *Buckman* Court's decision was based on a careful consideration of the delicate balancing act assigned to the FDA, which depends on its flexibility to address the sometimes competing concerns of adequately regulating new and existing products while also allowing

manufacturers the freedom to efficiently develop new products that could save lives, reduce, pain, or increase quality of life. *Buckman*, 531 U.S. 348, 349. The Supreme Court observed that the FDA's delicate balance would be disrupted by allowing state tort suits to enforce FDA regulations. For example, allowing all fifty states to impose and enforce their own interpretations of FDA regulations would damage "the comparatively speedy § 510(k) process . . . which would, in turn, impede competition among predicate devices and delay health care professionals' ability to describe appropriate off-label uses." *Id.* at 351.

A number of courts have applied *Buckman* to other state-law tort claims, such as failure to warn claims, and these courts have uniformly held that tort claims may proceed only when there basis is wholly separate from any federal regulatory violation. This is a matter of substance, not of form: "a private litigant cannot bring a state-law claim against a defendant when the state-law claim is in substance (even if not in form) a claim for violating the FDCA that is, when the state claim would not exist if the FDCA did not exist." *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 777 (D. Minn. 2009). And the substance of the claim must not depend on a regulatory violation:

> In other words, the conduct on which the claim is premised must be the type of conduct that would traditionally give rise to liability under state law -- and that would give rise to liability under state law even if the FDCA had never been enacted. If the defendant's conduct is not of this type, then the plaintiff is effectively suing for a violation of the FDCA (no matter how the plaintiff labels the claim), and the plaintiff's claim is thus impliedly preempted under *Buckman.*

Id.; see also Lefaivre v. KV Pharm. Co., No. 4:09CV00588SNLJ, 2010 WL 59125, at *3 (E.D. Mo. Jan. 5, 2010) ("Despite the nomenclature, this is not an action based on traditional state tort law that predated the FDCA regulation, because it is not an action that is brought independently of the federal violations. It is instead an action that is wholly dependent upon the federal violations and would not exist absent the federal violations. Under these circumstances, the cause

of action is impliedly preempted by federal law."); *In re Bayer Corp. Combination Aspirin Prods. Litig.* No. 09 Md. 2023 (BMC) (JMA), 2010 WL 1268196, at *8 (E.D.N.Y. Mar 30, 2010) ("In order to avoid preemption, however, a plaintiff's claim must thread the needle described in *Riley*, showing that defendant has violated the FDCA, but that plaintiff's claims are not entirely premised on that violation and that defendant's wrongdoing would entitle the plaintiff to recovery under traditional state law principles.").[15]

Thus, in order to establish a failure to warn claim, Plaintiff must establish an unreasonable failure to warn under common law principles, and not based upon any alleged regulatory violation. As the *Bayer* Court instructed in considering a misrepresentation claim, liability must "sound[] in traditional principles of state law and would give rise to recovery even had the FDCA never been enacted." *Id.* at 12. Thus, in *Bouchard v. American Home Prods. Corp.*, a federal court applied these principles and granted a "motion to exclude 'any evidence or argument that Wyeth "misled" the . . . "FDA" or "violated" the Food, Drug, and Cosmetic Act . . .'" 213 F. Supp. 2d 802, 811 (N.D. Ohio 2002). The court agreed that plaintiff could proceed on a claim "based on direct fraud against her and her healthcare provider," as to which "evidence concerning what information was and was not provided to the FDA might still be relevant." *Id*. at 812. But, as in *Bayer*, that evidence could not be used to argue that some alleged regulatory violation helped establish tort liability. Although the *Bouchard* court deferred to

[15] Each of these cases post-dates the Supreme Court's decision in *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), which followed the previously well-established rule that the MDA's express preemption provision "does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements." *Id*. at 330 (quoting *Lohr*, 518 U.S. at 495). As the *Riley* court explained, however, *Riegel*'s narrow permission of "parallel" state claims does not change the *Buckman* rule that state claims may not depend on evidence of regulatory violations. *Riegel* and *Buckman* require different analysis: "[E]ven if a claim is not *expressly* preempted by [the MDA] it may be *impliedly* preempted under *Buckman* …." *Riley*, 625 F. Supp. 2d at 776. "In sum, *Riegel* and *Buckman* create a narrow gap through which a plaintiff's state-law claim must fit if it is to escape express or implied preemption." *Id*. at 777. That gap requires that the plaintiff not rely on evidence of regulatory violations.

specific trial objections, it made clear that "evidence will be excluded outright when it is offered only to show that the FDA was misled, or that information was intentionally concealed from the FDA . . ." and that "[e]xclusion of further evidence may be necessary to prevent confusion of the jury as to the nature of [plaintiff's] claims." *Id.*[16]

Finally, it must be noted that just recently Judge Carol E. Higbee, presiding judge in the *Gross v. Gynecare, Ethicon, Inc.*, case, ATL-L-6966-10, found claims of fraud on the FDA to be preempted. Judge Higbee noted that: "including the *Buckman* decision which was cited, and other decisions, there's been a holding that a fraud against the Court when the argument is that a fraud existed against the FDA, that in fact that is preempted." (5906) Judge Higbee did not allow the *Gross* plaintiffs to attempt to prove wanton and willful conduct for purposes of punitive damages by showing a fraud on the FDA or by showing that FDA regulations were ignored. (Pg. 5907-5908.)

Bard's interaction with the FDA is one of the points of contention in this case.[17] Consequently, genuine issues of fact preclude summary judgment on this affirmative defense. Regardless, Plaintiff cannot predicate a claim on any alleged violation of FDA regulations because such a claim is barred by the preemption principles described in *Buckman*. Thus, as a safe-guard against a putative "fraud on the FDA" claim, Bard's preemption-related affirmative

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[16] *See also Skibniewski v. Am. Home Prods. Corp.*, No. 99-0842- CV-W-FJG, 2004 WL 5628157 at *13 (W.D. Mo. Apr. 1, 2004) (relying on *Buckman* and *Bouchard* to grant motion in limine to "Exclude Evidence Alleging that Wyeth Was Misleading or Deceptive in Its Dealings With the FDA and/or Committed Violations of the FDCA or the FDA Regulations"); *Swank v. Zimmer, Inc.*, No. 03-CV-60-B, 2004 WL 5254312, at *2 (D. Wy. Apr. 20, 2004) (relying on *Buckman* and *Bouchard* to grant motion in limine: "this Court will not allow Plaintiff to present evidence that Defendant misled the FDA by stating that the Device was subsequently equivalent to the Biomet Impact device allowing Defendant to forego a more stringent regulatory process and that Defendant failed to inform the FDA of certain testing.").

[17] For example, Plaintiff, through her regulatory expert witness David Kessler, argue that Bard was deceptive in its interactions with the FDA and violated FDA regulations. (*See* Kessler Report.) In contrast, Bard's regulatory expert, Paul Waymack, asserts that Bard fully complied with "all FDA regulations, guidances and industry standards in developing, designing, labeling, and marketing its various Avaulta products." (Waymack Report ¶ 172.)

defense cannot be dismissed. This is particularly true where, as here, Bard's regulatory expert witnesses have not yet been deposed.[18] Finally, Plaintiff's Motion on this point must fail because Bard is entitled to present evidence at trial that Bard fully complied with all of the applicable FDA laws, regulations, standards, and guidances, and nothing in Plaintiff's Motion should be used or construed to interfere with or otherwise abrogate that right.

CONCLUSION

For the reasons set forth above, Bard respectfully request the Court deny Plaintiff's Partial Motion for Summary Judgment in its entirety.

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Respectfully submitted,

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[18] Plaintiff has decided to reject the deposition dates originally offered by Bard. Inexplicably, Plaintiff has now opted to depose Bard's other regulatory expert witnesses by written question pursuant to Fed. R. Civ. P. 30(c)(3).

CERTIFICATE OF SERVICE

I hereby certify that on April 22, 2013, I caused the foregoing document to be electronically filed with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

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